REMARKS/ARGUMENTS

This is intended as a full and complete response to the Office Action dated September 17, 2007. Please reconsider the claims pending in this application for the reasons discussed below.

DISPOSITION OF CLAIMS

Claims 1-12, 14, and 30-35 are pending in this application. Claims 17 and 19-29 have been cancelled in an effort to advance prosecution of this application and without prejudice or disclaimer.

ELECTION/RESTRICTIONS

Applicant acknowledges that election of "pituitary adenylate cyclase polypeptide (PACAP)" as the polypeptide and "amino acid buffers" as the buffers is still in effect.

REJECTIONS UNDER 35 U.S.C. §103

Claims 1-12, 14-17, and 19-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Carpenter et al. (U.S. Patent No. 4806343), Andya et al. (U.S. Patent No. 6267958), Thomson, (U.S. Patent No. 4816440), Nishimura et al. (U.S. Patent No. 5861284), and Arimura et al. (U.S. Patent No. 5128242). Claims 17 and 19-29 have been cancelled. Accordingly, the rejection of these claims is moot. Reconsideration of the rejection of claims 1-12, 14-16, and 30-35 is respectfully requested.

Carpenter et al. disclose exposing protein to a carbohydrate and transition metal, and then freezing the protein. In the examples, the protein is exposed to the carbohydrate and transition metal under alkaline conditions. In Example I, PFK enzyme (protein) was dialyzed against sodium phosphate buffer containing dithiothreitol (pH 8.0). Then the enzyme stock was added to $ZnSO_4$ (source of Zn^{2+}) and trehalose (carbohydrate) in aqueous solution prepared in sodium phosphate buffer.

The examiner asserts that one of ordinary skill in the art would have had a reasonable expectation of success in including an amino acid buffer and/or a surfactant in the composition of Carpenter et al. because Andya et al. teach that amino acid

buffers and surfactants may be included in lyophilized compositions comprising any of numerous diverse proteins. Arguably, Carpenter et al. in view of Andya et al. teaches preparing protein for freezing by exposing the protein to a carbohydrate, a transition metal, and amino acid buffer and/or surfactant under alkaline conditions, and then freezing the protein.

The examiner asserts that Thomson teaches a stable composition comprising lyophilized interleukin-2. The examiner asserts that Thomson teaches that SDS maintains the stability of lyophilized proteins and that a person of ordinary skill in the art would have had a reasonable expectation of success in substituting SDS for the surfactants of Andya et al. Arguably, Carpenter et al. in view of Andya et al. and Thomson teaches preparing protein for freezing by exposing the protein to a carbohydrate, a transition metal, and amino acid buffer and/or surfactant under alkaline conditions, wherein the surfactant can be SDS, and then freezing the protein.

The examiner asserts that Nishimura et al. teach a composition for stabilizing polypeptides with an amide at their C-terminal or a disulfide linkage in the molecule, one of which is PACAP. The examiner asserts that the composition of Nishimura et al. is lyophilized and may further comprise trehalose as well as buffers, salts, and/or surfactants. The examiner asserts that one of ordinary skill in the art would have a reasonable expectation of success in substituting the PACAP of Nishimura et al. for the PFK of Carpenter et al. Arguably, Carpenter et al. in view of Andya et al., Thomson, and Nishimira et al. teaches preparing protein for freezing by exposing the protein to a carbohydrate, a transition metal, and amino acid buffer and/or surfactant under alkaline conditions, wherein the surfactant can be SDS and the protein can be PACAP, and then freezing the protein.

The examiner asserts that Arimura et al. teach that PACAP and fragments thereof have therapeutic activity. Arguably, Carpenter et al. in view of Andya et al. Thomson, Nishimira et al., and Arumura et al. teaches preparing protein for freezing by exposing the protein to a carbohydrate, a transition metal, and amino acid buffer and/or surfactant under alkaline conditions, wherein the surfactant can be SDS and the protein can be PACAP having therapeutic activity, and then freezing the protein.

However, the combination of these references does not teach stabilized polypeptide particles which are formulated to exhibit an acidic reconstitution pH, as recited in claims 1, 15, and 16. Paragraph [0028] of the specification as originally filed discloses that the solid-state polypeptide particles are formulated to exhibit an acidic reconstitution pH. The reconstitution pH is the pH exhibited by the polypeptide particles when the polypeptide particles are reconstituted. The reconstitution pH is therefore a property of the solid-state polypeptide particles. Paragraph [0032] of the specification as originally filed discloses that polypeptide particles having an acidic reconstitution pH are prepared from aqueous stabilizing solutions having an acidic pH. It is noted that not only do the protein formulations have to be prepared under acidic conditions to achieve the acidic reconstitution pH, but the carbohydrate and/or transition metal also have to be stable under the acidic conditions.

Carpenter et al. combined with Andya et al., Thomson, Nishmura et al., and Arimura et al., as described above, teaches preparing protein for freezing by exposing the protein to a carbohydrate, a transition metal, and amino acid buffer and/or surfactant under alkaline conditions. The examiner does not indicate why a skilled artisan seeking to prepare formulations according to the combination of these references would make any pH optimizations outside of the alkaline conditions, especially where formulation stability appears to be sensitive to the pH conditions in which it was prepared. On the other hand, paragraph [0028] of the specification as originally filed discloses that, "[b]y maintaining the polypeptide in an environment that favors protonation of the amino groups included in the polypeptide, it is believed that the polypeptide particles according to the first embodiment [i.e., solid-state polypeptide particles formulated to exhibit an acidic reconstitution pH] limit the involvement of amino groups in the formation of reactive intermediates and, as a result, limit the degradation of the polypeptide resulting from inter- or intra-molecular reactions."

From the foregoing, claims 1, 15, and 16 are not rendered unpatentable by Carpenter et al. combined with Andya et al., Thomson, Nishmura et al., and Arimura et al. Claims 2-12, 14, and 30-35, being dependent from claim 1, are also patentable in view of the foregoing arguments.

CONCLUSION

Applicant believes that this paper is fully responsive to the Office Action dated September 17, 2007, and respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
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Date: March 17, 2007

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